

REMARKS

Claims 1-10, 33-40, 52, and 61-75 are pending in the present application. By this amendment, claims 1, 3, 8-10, 31, 33, 38-40, 52, 64, 66, 71, 73, and 75 have been amended. Accordingly, claims 1-10, 33-40, 52, and 61-75 are currently under consideration. Applicant respectfully submits that these claims are allowable.

Interview Summary

Applicant thanks Examiner Sims for discussing the present application with Applicant's representative, Robert E. Scheid, by telephone on December 18, 2007. The issue of new matter in the Amendment filed October 19, 2007, was discussed. Agreement was reached that Applicant's representative would present arguments for further consideration with a Request for Continued Examination.

Objection to New Matter

According to an Advisory Action mailed November 20, 2007, the amendments filed October 19, 2007, were not entered because "they raise the issue of new matter." According to the Advisory Action, "Applicant's amendments to claims 1, 31, and 52 do not appear to have support in the instant specification, which raises the issue of introducing new matter. Support for the claim amendments of outputting to a user was not found at the referenced paragraphs of the specification, [0011] and [0150]. Therefore the amendment will not be entered."

Applicant respectfully submits that the specification does support the proposed amendments to claims 1, 31 and 52. For example, "outputs" are discussed at par. [0150] of the published application (2005/0125158 A1). Use of the model (e.g., by a "user") is discussed at par. [0011] of the published application.

The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the

invention as now claimed. See, e.g., *Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 USPQ2d at 1117. (MPEP 2163(I)(B))

In the present case, there is substantial support for the Applicant's possession of "outputting to a user." Applicant respectfully submits that there are numerous references to the use of the disclosed methods including access to the results (e.g., by the user of a computer): "The model may be used to simulate patients" (par. [0011]); "Tests can be applied to measure a feature at any time, and the raw result of the test is read directly from the value of the feature" (par. [0145]); "Because the values of all features are continuously available through the equations for trajectories, it is a relatively easy task to define models which determine occurrence of clinical events on the basis of evidence or customary practice" (par. [0146]); "This is followed by a series of exercises in which the parts of the model are tested and debugged-first one at a time, and then in appropriate combinations, using inputs that have known outputs" (par [0150]); "The calculations may be performed using distributed computing techniques" (par. [0150]); "In an embodiment of the present invention, four symptoms are tracked" (par. [0195]); "Each and every resource and its associated time and cost may be tracked for every patient." (par. [0265]); "The present invention has significant advantages over the prior art. It is able to analyze guidelines , performance measures, the what-to-do parts of disease management programs, clinical priorities, medical necessity, and coverage policies, at the level of detail at which they are written, and at which clinicians debate these issues" (par. [0304]).

Further, Applicant respectfully points out that the original specification included claims drawn to an "apparatus" (e.g., claim 22) and a "program storage device readable by a machine, tangibly embodying a program of instructions executable by the machine to perform a method" (e.g., claim 53). Further, each of Figures 22-30 is presented as an illustration of an apparatus (pars. [0030] –[0038]). Applicant respectfully submits that this disclosure provides inherent support for "outputting to a user."

By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily

discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973). (MPEP 2163.07(a))

Applicant respectfully requests that the above-cited objection to new matter be withdrawn so that the pending claims can be examined as amended herein.

Claim Rejections under 35 USC § 101

Claims 1-10, 31-40, 52 and 61-75 stand rejected under 35 USC § 101 because the claimed invention is directed to non-statutory subject matter. Claims 1, 31, and 52 have been amended to include limitations for “*outputting at least one value for the virtual patient’s FPG at time t to a user.*”

Applicant respectfully requests that the above-cited rejection under 35 USC § 101 be withdrawn.

Claim Rejections under 35 USC § 112 (second paragraph)

Claims 1-10, 31-40 and 61-75 stand rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The claims have been amended for clarity.

Claim 3 has been amended to so that “*the parameters a, b, c, and d are set to fit data for a population that is represented by the virtual patient.*” Claims 8-10, 33, 38-40, 66, 71, and 73 have been similarly amended.

Claim 64 has been amended to depend from claim 33. Claim 75 has been amended to depend from claim 66. Claim 71 has been amended to remove the erroneous dependency on claim 7.

Applicant respectfully requests that the above-cited rejection under 35 U.S.C § 112, second paragraph, be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **14-1437** referencing docket no.**8223.002.CPUS02**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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